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DURECT CORPORATION
THOMAS P. MCCRACKEN
2 RESULTS WAY
CUPERTINO, CA 95014

EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/737,144	YUM ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,10-50 and 52-79* is/are pending in the application.

4a) Of the above claim(s) *32-40,52,53,56 and 65-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8,10-31,41-50,54,55,57-64 and 68-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/24/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner acknowledges receipt of request for extension of time, amendment and remarks filed 12/24/09. No claim is amended. Claim 54 is canceled. Claims 1, 2, 4-8, 10-50 and 52-79 are pending. Claims 32-40, 52, 53, 56 and 65-67 are withdrawn from consideration.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Clarification of claims status

2. Claim 54 has been canceled by the present amendment.

3. Claims 32-40, 52, 53, 56 and 65-67 are withdrawn from consideration and were in advertently included in the listing of claims rejected.

4. Claim 79 is directed to formulation comprising SAIB (sucrose acetate isobutyrate), CAB (cellulose acetate butyrate), IPM (isopropyl myristate), EL (ethyl lactate) and opioid. This claim is of the same scope as claim 61 except that claim 61 is a oral dosage form and claim 79 is a delivery device so that the two claims were not held as duplicate of each other. Claim 61 was rejected and as such claim 79 should have been included in the listing of the claims. The omission of claim 79 was inadvertent.

5. Therefore, to address the issue of trade mark in claims 12 and 57 and also to properly identify the claims rejected and claims withdrawn, the rejection is made non-final.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 12 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 12 and 57 contain the trademark/trade name MIGLIOL 810. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe caprylic/capric triglycerides and, accordingly, the identification/description is indefinite.

9. Trademark designates source of goods, and not the goods/content themselves; a product could change formula and still maintain the mark; Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name, hence rendering the claimed invention indefinite.

10. Correction is respectfully requested.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 2, 4-7, 10-18, 29, 30, 46-50, 55, 57, 61, 63-68, 70, 71 and 73-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Tipton et al. (US 5,747,058).

13. Tipton discloses a composition comprising drug such as codeine (column 7, line 62, the pharmacological agent is not limited), HVLCM such as SAIB (column 3, lines 1-23; column 6, line 39; column 8, lines 50-54; column 10, lines 23-30), Solvents such as ethyl lactate (EL), which is one of the preferred (column 10, lines 23-30), and various additives namely biodegradable polymers, non biodegradable polymers such as CAB, oils and fats such as fatty acid esters, carbohydrates and carbohydrate derivatives (column 9, lines 7, 28, 40, 41, 42). Tipton cautions that oils such as "glycerol, corn oil … super refined peanut oil" are not preferred for use with SAIB (column 10, lines 27-30) and when talking about delivery systems names

isopropyl myristate (IPM) as preferred fatty acid ester for use with SAIB (column 12, lines 34-37).

14. Codeine meets the drug and opioid limitations of claims 1, 29, 30, 61, 63, 70, 71, 78 and 79. Claim 10 and 11, 46-50 recite the properties of the composition and are thus met; IPM meets claims 1, 12, 61, 62, 74, 78 and 79; EL meets claims 1, 55-57, 61, 62, 70, 76, 78 and 79. Additives such as preservative, antioxidants, stabilizers, vitamins (column 12, line 65 to column 13 line 4) are present and the antioxidants meet claims 17, 18. The Tipton composition comprising drug or codeine, IPM, CAB, HVLCM, EL and SAIB meets claims 1, 61, 70, 77-79.

15. Claims 46-50, 75 recite the properties of the composition, also the recitation that the composition upon exposure to aqueous environment forms a network as recited in claims 1 and 77, effective to reduce rate of extraction of the drug and simultaneously providing desirable release kinetics are also the characteristic of the composition so that the composition of Tipton would inherently possess these properties/characteristics.

16. Claim 77 is rejected under 35 U.S.C. 102(b) as being anticipated by Molinoff et al. (US 6,312,217).

17. The drug delivery device of Molinoff comprises a composition/formulation (claims 13 and 16) and anticipates the drug delivery device of claim 77. A formulation that "upon exposure to an aqueous environment, forms a network within the formulation and an outer surface" is the characteristic of the composition.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 1, 2, 4-8, 10-31, 41-50, 55, 57-64, 68-76, 78 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tipton et al. (US 5,747,058).

21. Tipton discloses a composition comprising HVLCM, and with sucrose acetate isobutyrate specifically employed (abstracts, column 2, lines 43, 46, 55, 60-65; column 4, lines 2-67; column 5, lines 1-33; column 8, lines 51-67; column 12, lines 46-50) meeting the recitation of HVLCM in the claims, specifically claims 1, 4, 5, 19-22, 70 and 78; the composition contains surfactants (column 11, lines 40-67; column 12, lines 1-17) in amounts of 0.5-30% and having 1-5% preferred that encompasses the amount of the network former of the claims and specifically claims 26-29 in terms of the % amounts but also meets the generic limitation of network formers

in claims 1, 2, 4, 6, 26-29, 70, 73, 77 and 78; oily components (column 12, lines 18-45) in amounts of 0.5-50% and with 1-10 preferred meeting the rheology modifier of the claims and specifically claims 23-25 in terms of the % amounts and also meets the generic limitation of rheology modifier of claims 1, 10, 11, 23-25, 70 and 78; water or DMSO or ethyl lactate or triacetin (column 2, lines 49 and 50; column 12, line 51) meeting the solvent requirements of the claims, specifically claims 1, 55, 57-62, 69, 70, 76, 78 and 79; additives such as preservative, antioxidants, stabilizers, vitamins (column 12, line 65 to column 13 line 4) meeting claims 17 and 18, and drugs such as codeine (column 7, line 62) meeting claims 29, 30, 70, 71; the formulation of Tipton is placed in gelatin capsules for oral administration (claim 88) meeting claims 13-16. Claims 46-50, 75 recite the properties of the composition, also the recitation that the composition upon exposure to aqueous environment forms a network as recited in claims 1 and 77, effective to reduce rate of extraction of the drug and simultaneously providing desirable release kinetics are also the characteristic of the composition so that the composition of Tipton would inherently possess these properties/characteristics. The composition of Tipton would inherently possess the characteristics of the composition recited in claims 2 and 4.

22. Tipton describes compositions that contain CAB and HVLCM and solvents separately (see column 4). Regarding the amounts of HVLCM recited in claims 19-22, in the absence of factual evidence, the claimed amounts are not inventive over the prior art. Regarding the amounts of the drugs, it is noted that Tipton teaches percent amounts of drugs and the specific amounts recited in claims 41-45 are not inventive over the percent amounts taught by Tipton in the absence of factual showing of unexpected results. Furthermore, regarding claims 25 and 16, it is noted that the composition of Tipton is encapsulated and use of soft and hard gelatin

capsules are known in the art so that it would be obvious to place the formulation in soft or hard gelatin capsule for delivery. Tipton clearly teaches that the composition contains **additives** that modifies the properties of the composition as desired (column 3, lines 31-44); the additives are A) biodegradable polymers and combinations and one or more of these bodegradable polymers can be use (column 9, lines 8-27), B) Non-biodegradable polymers, with CAB and CAP preferred (column 9, lines 28-41), C) oils and fats (column 9, lines 42-60), D) carbohydrates and carbohydrate derivatives (column 9, lines 61-67). The composition of Tipton contains HVLCM, drugs and solvent and when SAIB is the HVLCM, the solvent is ethyl lactate, EL, ethyl acetate, benzyl alcohol, triacetin, N-methylpyrrolidone, propylene carbonate and glycofurol are preferred (column 10, lines 23-30) and these solvents are used in amounts of 5-55% (column 10, lines 31-37). One of the drugs in Tipton is codeine, which is an opioid. Tipton does not teach the oxycodone in claims 31, 63, 64 and 72. Since oxycodone and codeine are opioids, and specifically, oxycodone is derived from codeine, it is prima facie obvious that oxycodone can be used in place of codeine and expect to obtain similar relative potency. Thus, when the composition of Tipton contains sucrose acetate isobutyrate (SAIB), cellulose acetate butyrate (CAB), isopropyl myristate (IPM), ethyl lactate (EL) and opioid, then claims 61, 62, 78 and 79 are specifically met.

23. Tipton teaches these HVLCM, drugs, solvent and additives are formulated and that the additives are added as desired to modify the properties. For example, oils are added to retard degradation and water uptake (column 9, lines 58-60) and isopropyl myristate, octyl palmitate, ethyl oleate, ethyl palmitate are preferred fatty acid esters (column 12, lines 34-40).

24. Tipton is described above as anticipating claims 1, 2, 4-7, 10-18, 29, 30, 46-50, 55, 57, 61, 63-68, 70, 71 and 73-79. Tipton does not teach the specification for the CAB recited in claim 8. But the %amounts of the butyryl content, acetyl content and the hydroxyl content in the ranges recited contents that are determinable and would be associated with a CAB.

25. There is however, no demonstration in applicant's specification that CAB that is comprised of about 17-38% butyryl, about 13-30% acetyl and about 0.8-1.7% hydroxyl content provides unexpected result to the composition. Because, CAB is comprised of butyryl, acetyl and hydroxyl components, the artisan has the technical skills of determining the %amounts of the various components.

26. Therefore, taking the teachings of Tipton, one having ordinary skill in the art at the time the invention was made would expect that using CAB comprised of various percent amounts of the constituent components of butyryl, acetyl and hydroxyl with HVLCM/SAIB, EL, IPM and drug in the composition of Tipton would be reasonably expected to yield a composition that an effective and successful controlled release dosage/composition/device for the drug.

Response to Arguments

27. Applicant's arguments filed 12/24/09 have been fully considered but they are not persuasive.

28. In paragraph *(A)* of the remarks, applicant argues that when the claimed invention is considered as a whole, one would fine that the invention provides unexpected beneficial performance characteristics discovered by the applicant by combining "particular set of pharmaceutical excipient" in oral controlled release formulation that provides for long term

delivery of potent and potentially dangerous drugs, such as between 1-20 hours or greater, that provides resistance to unwanted extraction of the entire drug dose using solvents such as water and ethanol as shown in the instant application at paragraphs [0045], [0049], [0059], [0062], [0070], [0077]-[0083] of the published application; that provides favorable drug release kinetics during transit through the gastro-intestinal tract when the dosage form is taken as intended thereby decreasing the number of time the drugs must be administered, that provides safe formulations that are less susceptible to abuse, including extraction into water or ethanol, than the prior art tablet or capsule. Applicant thus states that the claimed invention in claim 1 and the claims dependent from claim 1, claims 70, 78 and 79 contain the express combination of 7 basic elements namely: (a) oral dosage form or drug delivery device, (b) containing a formulation that forms a network within the formulation and an outer surface when contacted with an aqueous environment, the formulation includes (c) a drug, (d) HVCLM, (e) network former, (f) rheology modifier, and (g) solvent.

29. Response: The examiner agrees that the claimed formulation comprises (c) a drug, (d) HVCLM, (e) network former, (f) rheology modifier, and (g) solvent and any composition of the prior art that comprises (c) through (g) which is an oral dosage form (a) would have the property of forming a network within the formulation and an outer surface when contacted with an aqueous environment, which is (b). Thus a capsule or tablet of the prior art that comprises (c) through (g) would also have the characteristic advantage applicant is arguing for because same products must have the same properties. The prior art teaches dosage form in capsule form comprising the specific solvent, ethyl lactate; specific network former, CAB; specific HVLCM, SAIB; specific rheology modifier, IPM; and drug. Thus the composition of Tipton being a

capsule is an oral formulation and would have the characteristic of (b) that is the formulation would be capable of forming a network within the formulation and an outer surface when contacted with an aqueous environment. The claimed composition in claims 1, 70, 77, 78 and 79 is disclosed by Tipton as describe in the rejections above.

30. In paragraph *(B)* of the remarks, applicant argues that (i), Tipton does not disclose the expressly recited combinations and the office action at page 5, second paragraph admits that Tipton does not disclose one composition that contains HVLCM, CAB, solvent and rheology modifier; (ii) Tipton does not describe the formulations as having applicant's recited properties and that the office failed to identify a particular composition that would have the recited properties; (iii) Tipton does not disclose the problem that applicant sought to solve.

31. Response: (i) On page 5, second paragraph of the office action of 6/25/09, the examiner noted that, "Tipton does not exemplify one composition that has HVLCM, CAB, solvent, and rheology modifier," and it is because there is no exemplification of one formulation that has the HVLCM, CAB, solvent, and rheology modifier, and drug that the rejection was made under 35 USC 103 and not under 35 USC 102. Tipton teaches all the components of the claimed dosage form so that there is a strong suggestion to combine the disclosed components in one dosage form. Tipton does not exclude any of the disclosed components from being put together in one composition. A prior art is not limited to the examples. Therefore, applicant's arguments with respect to (i) is not persuasive because the prior art is not limited to the examples but the reference as a whole has been considered. (ii) While the examiner agrees that Tipton does not expressly state the properties of the composition, a compositions and their properties cannot be separated. Tipton teaches at least the generic claims directed to broad compositions containing

solvent, ethyl lactate; network former, CAB; HVLCM, SAIB; rheology modifier, IPM; and drug, which is the composition claimed in claims 1, 61, 70, 78 and 79 and because same composition must have the same properties, the composition of Tipton must have the recited properties. (iii) Applicant has argues that a problem with drug extraction was solved by the current dosage form and that Tipton does not recognize the problem that needed to be solved. However, the prior art does not have to recognize the problem that needed to be solved; in the present case, Tipton discloses the claimed dosage form and the properties of the composition cannot be separated form the composition so that those properties recognized by applicant to be the problem solved are also attendant in the prior art composition. Furthermore, applicant has not provided a showing that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references, they would still be unable to solve the problem. See MPEP § 716.04. Also, because, the prior art dosage form would suffer the same fate or has the same characteristic in being the same composition as claims 1, 61, 70, 78 and 79, it flows that what applicant deems problem that needed to be solved has been solved.

32. In paragraph *(C)* of the remarks, applicant argues the Office has used impermissible hindsight in rejecting the claims because the office action picked ands chose elements form unrelated laundry lists of optional additives that Tipton teaches can be employed with the HVLCM and that the Office has not demonstrated that the cited art teaches or suggests all the claimed limitation; applicant supports this view by citing KSR.

33. Response: The office action did not employ impermissible hindsight in the rejections. Particularly, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the present case, Tipton teaches a capsule (oral delivery system) that comprises drug, HVLCM, solvent and a variety of optional additives and these additives modify the properties of the composition; variety of optional additive is not a teaching that only one additive is used and optional inclusion of additives is a positive teaching that the composition may contain the additive and the composition may not contain the additive. Further, when the additive is a non-biodegradable polymer, CAB, CAP, polyethylene, polyvinyl pyrrolidone, ethylene vinyl acetate, polyethylene glycol are preferred and selecting CAB from a list of 6 is not a picking and choosing and a list of seven is not a laundry list. With regards to the solvent, ethyl lactate, ethyl acetate, benzyl alcohol, triacetin, N-methylpyrrolidone, propylene carbonate and glycofural are recommended for use with SAIB HVLCM (see, column 10, lines 23-26) and any of the seven solvents can be used and the list of seven is not a laundry list. By the same token, the list of oils and fats that meet the limitation of rheology modifier is not a laundry list. Therefore, just as it was shown in the rejections, the Office demonstrated that Tipton disclosed the claimed dosage form comprising SAIB, CAB, IPM, EL and rheology

modifier. The burden shifted to applicant to show that the Tipton disclosed otherwise and applicant has not shown that Tipton does not disclose a composition.

34. MPEP 2143 states "when there is motivation to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." Therefore that the skilled artisan would have had reason to try these methods with the reasonable expectation that at least one would be successful.

35. With regards to KSR, the court in the KSR case was clear that a fact finder should not be denied common sense in approaching the prior art as it relates to claimed invention and that "when a structure already known in the prior art is altered by mere substitution of one of the elements for another known in the field, the combination must do more than yield a predictable result." In the present case, the language of the claimed dosage form or dosage delivery device is comprising and open so that the suggestion to add III, which is a variety of optional additives listed as biodegradable polymers, non-biodegradable polymers, oils and fats, carbohydrate and carbohydrate derivatives to I (HVLCM), II (substance to be delivered), IV (Solvent) is a strong suggestion that the composition comprising I (HVLCM), II (substance to be delivered) and IV (Solvent) can contain the additives.

36. In paragraph *(D)* of the remarks, applicant argues that the Office failed to show a reasonable expectation of success.

37. Response: The examiner disagrees because if the claimed dosage form is a solution to a problem that applicant has not shown the efforts that have been expended so far, then the

disclosed dosage form of Tipton had solved the problem before applicant's invention. If the claimed dosage form comprising HVLCM, CAB, IPM, EL and opioid restricts the abuser form defeating the release of actives within 8, 12, or 24 hours, then the dosage of Tipton comprising, HVLCM, drug, EL, CAB and IPM had achieved the same goal before applicant's invention. Applicant has not demonstrated that the composition of Tipton cannot provide the sustained release pharmacokinetics and applicant has not shown that the claimed dosage capsule is safer than the capsule of Tipton. Paragraphs [0120]-[0129] is not a comparison of the claimed dosage form with the dosage form of Tipton. The in re Dillon case supports the current rejection because, it is said that Federal Circuit case law prior to the Supreme Court's decision in KSR is generally in accord with these statements by the KSR Court. And, the In re Dillon, 919 F.2d 688, 693, 16 USPQ2d 1897, 1902 (Fed. Cir. 1990) (en banc) states ("[I]t is not necessary in order to establish a prima facie case of obviousness that both a structural similarity between a claimed and prior art compound (or a key component of a composition) be shown and that there be a suggestion in or expectation from the prior art that the claimed compound or composition will have the same or a similar utility as one newly discovered by applicant"), which supports the case made in the rejections.

38. In paragraph *(E)* of the remarks, applicant argues that the proper consideration of the Graham factual inquiries demonstrates that the office has failed to establish a prima facie case of obviousness.

39. Response: While the supreme court in KSR reiterated the frame work of the Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that obviousness is a question of law based on underlying factual inquiries, the KSR court also stated that "TSM" inquiry is not the only

rationale and found that the Federal Circuit erred in four ways namely: "(1) "by holding that courts and patent examiners should look only to the problem the patentee was trying to solve " (Id. at ___, 82 USPQ2d at 1397); (2) by assuming "that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem" (Id.); (3) by concluding "that a patent claim cannot be proved obvious merely by showing that the combination of elements was obvious to try'" (Id.); and (4) by overemphasizing "the risk of courts and patent examiners falling prey to hindsight bias" and as a result applying "[r]igid preventative rules that deny fact finders recourse to common sense" (Id.).

40. Therefore, the pending claims are not allowable. The office action had not advocated modifying properties of a composition --- those properties are innate to the composition.

41. No claim is allowed.

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

43. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

44. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618